



TFW

Patitioner's Docket No. 700355-053462-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kaplan et al.
Application No.: 10/541,182
Filed: January 7, 2004
Group No.: To be assigned
Examiner: To be assigned
Customer No.: 50828
For: SILK FIBROIN MATERIALS AND USE THEREOF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8(a) and 1.10)

I hereby certify that this correspondence:

1. Certificate of Mailing (1 pg.);
2. Transmittal Form (1 pg.);
3. Information Disclosure Statement with Forms 08a and b (3 pp.);
4. COPY – References A1-A4, B1, B2 and C1-C20; and
5. Return Receipt Postcard.

is on the date shown below being:

MAILING

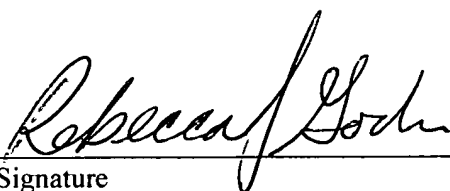
X deposited with the United States Postal Service
with sufficient postage as first class mail in an
envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313.

Date: January 24, 2006

FACSIMILE

transmitted by facsimile to the Patent and
Trademark Office.


Signature

Rebecca J. Goodwin
(type or print name of person certifying)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

	Application Number	10/541,182	
	Filing Date	January 7, 2004	
	First Named Inventor	David L. Kaplan	
	Art Unit		
	Examiner Name		
Total Number of Pages in This Submission		7	
		Attorney Docket Number	700355-053462

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Certificate of Mailing; Copy of References A1-A4, B1, B2 and C1-C20; and Return Receipt Postcard
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Nixon Peabody, LLP		
Signature			
Printed name	David S. Resnick		
Date	1/24/06	Reg. No.	34,235

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature			
Typed or printed name	Rebecca J. Goodwin	Date	01/24/2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kaplan, et al.

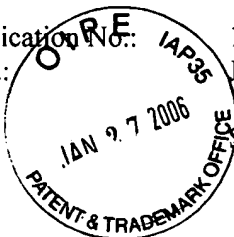
Application No.: 10/541,182
Filed: January 7, 2004

Group No.: To be assigned

Examiner: To be assigned

Customer No.: 50828

For: SILK FIBROIN MATERIALS AND USE THEREOF



CERTIFICATE OF MAILING (37 C.F.R. SECTION 1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

1-24-06
Date

Rebecca J. Goodiwn
(type or print name of person mailing paper)

Rebecca J. Goodiwn
(signature of person mailing paper)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §§1.56 and 1.97, Applicants herewith submit the publications and/or patents shown on the attached form PTO-1449, for consideration by the Examiner in connection with the examination of the above-identified patent application.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

- X (1) within three (3) months of the Filing Date or **before the mailing date of the First Office Action** on the merits; or
- (2) within three months of the mailing date of the PCT International Search Report; or
- (3) after the period defined in (1) but before the mailing date of a **Final Rejection or Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or

— (4) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

— (5) A copy of the International Search Report – Form PCT/ISA/210 is enclosed herewith.

It is respectfully requested that each of the documents shown on the attached form(s) PTO-1449 be made of record in this application. Copies of these documents (CHECK ONE):

 X are enclosed herewith; and
— have been cited in the parent application, and are thus not being resubmitted herein.

Early examination and allowance of the present application are respectfully solicited.

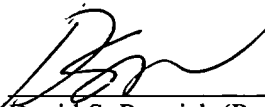
FEE AUTHORIZATION

Should any fees associated with the submission of this document be required, the Commissioner is authorized to charge the missing fee to our Deposit Account No. 50-0850. Any overpayments should be credited to said Deposit Account.

Date: 1/24/06

Respectfully submitted,

Customer No. 50828



David S. Resnick (Reg. 34,235)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110-2131
(617) 345-6057

Complete if Known

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/541,182
		Filing Date	01/07/2004
		First Named Inventor	David L. Kaplan
		Art Unit	
		Examiner Name	
Attorney Docket Number	700355-053462		

[illegible]

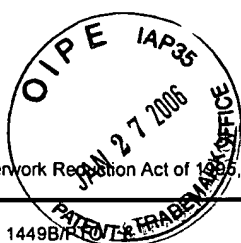
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
	B1	WO	01/54667 A1	08/02/2001	Smithkline Beecham Corporation		
	B2	WO	01/80921 A2	11/01/2001	Emory University		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08b (07-05)
Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/P

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

Application Number	10/541,182
Filing Date	01/07/2004
First Named Inventor	David L. Kaplan
Art Unit	
Examiner Name	
Attorney Docket Number	700355-053462

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	ANTHANASIOU, ET AL., "Sterilization, toxicity, biocompatibility and clinical applications of polylactic acid/polyglycolic acid copolymers," Biomaterials, 1996, Vol. 17 (No.), p. 93-102,	
	C2	BOGNITZKI, ET AL., "Nanostructured Fibers via Electrospinning," Adv Mater, 2001, Vol. 13 (No. 1), p. 70-72,	
	C3	BOLAND, ET AL., "Electrospinning of Tissue Engineering Scaffolds," Polymeric Materials: Science & Engineering, 2001, Vol. 85 (No.), p. 51-52,	
	C4	CATERSON, ET AL., "Three-dimensional cartilage formulation by bone marrow-derived cells seeded in polylactide/alginate amalgam," Biomed Mater Res, 2001, Vol. 57 (No.), p. 394-403,	
	C5	DAL PRA, ET AL., "Silk Fibron-Coated Three-Dimensional Polyurethane Scaffolds for Tissue Engineering: Interactions with Normal Human Fibroblasts," Tissue Engineering, 2003, Vol. 9 (No. 6), p. 1113-1121,	
	C6	DOSHI, ET AL., "Electrospinning Process and Applications of Electrospun Fibers," Journal of Electrostatics, 1995, Vol. 35 (No.), p. 151-160,	
	C7	HOLY, ET AL., "Use of a biomimetic strategy to engineer bone," J Biomed Mater Res, 2003, Vol. 65A (No.), p. 447-453,	
	C8	HUTMACHER, "Scaffolds in tissue engineering bone and cartilage," Biomaterials, 2000, Vol. 21 (No.), p. 2529-2543,	
	C9	JIN, ET AL., "Electrospinning Bombyx mori Silk with Poly(ethylene oxide)," Polymer Preprints (American Chemical Society, Division of Polymer Chemistry), 2002, Vol. 43 (No. 2), p. 743-744,	
	C10	KARP, ET AL., "Fabrication of Precise Cylindrical Three-Dimensional Tissue Engineering Scaffolds for In Vitro and In Vivo Bone Engineering Applications," The Journal of Craniofacial Surgery, 2003, Vol. 14 (No. 3), p. 317-323,	

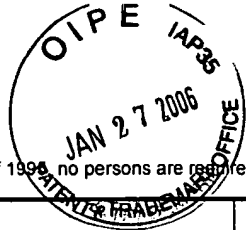
Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/541,182
Filing Date	01/07/2004
First Named Inventor	David L. Kaplan
Art Unit	
Examiner Name	
Attorney Docket Number	700355-053462

Sheet 2 of 2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C11	LI, ET AL., "Study on Porous Silk Fibroin Materials. I. Fine Structure of Freeze Dried Silk Fibroin," J Appl Polym Sci, 2001, Vol. 79 (No.), p. 2185-2191,	
	C12	MARTIN, ET AL., "Selective differentiation of mammalian bone marrow stromal cells cultured on three-dimensional polymer foams," J Biomed Mater Res, 2001, Vol. 55 (No.), p. 229-235,	
	C13	NAM, ET AL., "Morphology of Regenerated Silk Fibroin: Effects of Freezing Temperature, Alcohol Addition, and Molecular Weight," J Appl Polym Sci, 2001, Vol. 81 (No.), p. 3008-3021,	
	C14	OHGUSHI, ET AL., "Calcium Phosphate Block Ceramic With Bone Marrow Cells in a Rat Long Bone Defect," CRC Handbook of Bioactive Ceramics, Vol. II (No.), p. 235-238,	
	C15	PEREZ-RIGUEIRO, "Silkworm Silk as an Engineering Material," J Appl Polym Sci, 1998, Vol. 70 (No.), p. 2439-2447,	
	C16	PETITE, ET AL., "Tissue-engineered bone regeneration," Nature Biotechnology, 2000, Vol. 18 (No.), p. 959-963,	
	C17	SOFIA, ET AL., "Functionalized silk-based biomaterials for bone formation," J Biomed Mater Res, 2000, Vol. 54 (No.), p. 139-148,	
	C18	STITZEL, ET AL., "Aterial Smooth Muscle Cell Proliferation on a Novel Biomimicking, Biodegradable Vascular Graft Scaffold," J Biomater Appl, 2001, Vol. 16 (No.), p. 22-33,	
	C19	ZARKOOB, "Structure and Morphology of Regenerated Silk Nano-Fibers Produced by Electrospinning," A Dissertation Presented to The Graduate Faculty of the University of Akron, August 1998,	
	C20	ZARKOOB, "Structure and Morphology of Nano Electrospun Silk Fibers," Polymer Preprints (American Chemical Society, Division of Polymer Chemistry), 1998, Vol. 39 (No. 2), p. 244-245,	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.